

JUN - 1 2007

K071358

510(k) Summary

Submitter Information

Applicant/Owner: Radiant Medical, Inc.
250 Chesapeake Drive
Redwood City, CA 94063
(650) 363-8000

Contact Person: Scott A. Wilson, Ph.D.
Vice President of Regulatory Affairs, Quality Assurance &
Intellectual Property

Summary Date: May 2007

Name and Classification

Proprietary Name: The Reprieve[®] Endovascular Temperature Therapy System

Regulation Name: Thermal regulating system

Regulation No.: 870.5900

Class: II

Product Code: NCX

Predicate Devices

- a) The Radiant Medical Reprieve[®] Endovascular Temperature Therapy System cleared under K012512 (decision dated June 11, 2002) and special K063405 (decision dated January 8, 2007).
- b) The Innercool Celsius Control System[™] cleared under K022366 (decision dated January 27, 2003).
- c) The Alsius CoolGard[®] and CoolLine[®] Catheter Thermal Regulation System cleared under K030421 (decision dated October 23, 2003).

Indication for Use

The Radiant Medical Reprieve® Endovascular Temperature Therapy System is a thermal regulating device intended to induce, maintain, and reverse mild hypothermia in neurosurgical patients in surgery and in recovery/intensive care.

Description of Device

The Reprive System consists of a single-use, heparin-coated, central venous catheter; a single-use, heat exchange cassette; an integrated temperature probe; and an external controller. The Controller unit has a user interface to select operating parameters and is connected to the Catheter via the Cassette and extension lines. The catheter is designed for placement in the inferior vena cava via the femoral vein using a 12 Fr hemostatic introducer sheath.

Summary of Technological Characteristics

The Reprive System uses established technology, materials, and construction techniques. The system employs standard heat conduction and convection technology to warm or cool the blood using circulating warm or cool sterile saline within a balloon catheter in a closed loop system. Heat exchange is achieved without direct contact between the circulating saline and the patient's blood. The saline is continuously circulated in the closed loop through the catheter, placed in the inferior vena cava via the femoral vein, thereby exchanging heat with the blood by means of counter current heat exchange with the blood flow. The saline is returned from the catheter through an insulated extension line to a disposable cassette (plugged into the controller) where the heat from the saline is exchanged across a second heat exchange surface with a thermal transfer (process) fluid circulating in the controller. The temperature of the process fluid, which governs the degree and rate of heat exchange, is controlled based on the patient's temperature. The controller continuously monitors the patient temperature by a temperature probe (K042388) placed through the guide wire lumen of the heat exchange catheter and through a feedback loop, ensuring that a patient remains at the target temperature.

Performance Test

The Reprive Endovascular Temperature Therapy System has been tested for system performance substantially equivalent to the predicate devices. In addition the Catheter has been tested for functionality in accordance to BS EN ISO 10555, for biocompatibility in accordance to ISO 10993, and for sterility in accordance to ISO 11137. The controller has been tested for electrical safety in accordance to IEC 60601.

Conclusion

Descriptive information and appropriate performance data demonstrate that the Radiant Medical Reprive Endovascular Temperature Therapy System performs with safety and effectiveness substantially equivalent to the predicate devices for the stated indication for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Radiant Medical, Inc.
% Scott A. Wilson, Ph.D.
Vice President, Regulatory
Affairs and Quality Assurance
250 Chesapeake Drive
Redwood City, California 94063-4745

JUN - 1 2007

Re: K071358
Trade/Device Name: Reprieve[®] Endovascular Therapy System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: NCX
Dated: May 14, 2007
Received: May 16, 2007

Dear Dr. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Scott A. Wilson, Ph.D.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Reprive® Endovascular Temperature Therapy System

Indications for Use:

The Radiant Medical Reprive® Endovascular Temperature Therapy System is a thermal regulating device intended to induce, maintain, and reverse mild hypothermia in neurosurgical patients in surgery and in recovery/intensive care.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K071358